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I, LEANNE MYNOTT, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PQ5182 for a patent by EFFEM FOODS PTY LTD filed on 20 January 2000.



WITNESS my hand this Fourth day of October 2000

L.Aff

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Patents Act 1990

# **ORIGINAL**

# PROVISIONAL SPECIFICATION

PET FOOD PRODUCT AND PROCESS FOR MANUFACTURING SAME

The invention is described in the following statement:

## PET FOOD PRODUCT AND PROCESS FOR MANUFACTURING SAME

#### Field of th Invention

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This invention relates to a pet food product, particularly a palatable pet food product containing functional additives which have health-enhancing properties.

This invention also relates to a process for manufacturing a palatable pet food product containing such functional additives.

## **Background of the Invention**

Typical pet food products satisfy a pet animal's basic dietary requirements.

However, like other creatures, pet animals suffer various ailments and health conditions and often require appropriate forms of medication and/or other treatment. Generally, medications and remedies for pet animals are provided in the form of tablets, powders or liquids which can be administered directly to the pet animal. However, many pet animals are reluctant to take such tablets, powders or liquids and having to force these into the animal's mouth can be stressful for both the animal and the owner.

Alternatively, especially if the medication or remedy is unpleasant-tasting, it can be added to and mixed with the animal's meal, so as (hopefully) to mask the unpleasant taste. However, this procedure is inconvenient, cumbersome, imprecise and subject to human error (e.g. spillage and miscalculation).

Some pharmaceutical medications for pet animals have been provided mixed with a pet food type product, primarily for the purpose of masking the taste of the pharmaceutical medication. Typically, the pharmaceutical medication is added to the pet food by the manufacturer so that the pet owner does not need to engage in this mixing exercise. For instance, some pet food type products exist which incorporate synthetic pharmaceutical drugs (e.g. Exelpet<sup>TM</sup>, Ezy-dose All Wormer and Heartguard<sup>TM</sup>). These products are essentially pharmaceutical or medicinal products which are not intended to be substitutes for the pet animal's usual meal. When the course of treatment is over and the pet animal's health concerns have been rectified, the administration of the relevant food/pharmaceutical mixture generally ceases.

Accordingly, such products are generally only used spasmodically as a short term treatment regime for a pet animal's illness.

Also, a significant problem with providing a pharmaceutical medication as part of a pet meal is that it does not allow for easy administration of dosage amounts of the pharmaceutical medication. Dosage requirements will vary depending on the size of the pet animal and its health condition. A large pet animal is likely to require higher quantities of the medication than a small pet animal. However, pharmaceutical-containing commercial pet meals are generally sold in tins or packets of standard sizes and no real guidance is given for varying the dosage of the medication administered to the pet animal so as to be appropriate for the size and/or health condition of the pet animal.

Also, it is now generally accepted that herbal remedies are beneficial in treating or ameliorating various human ailments. Similarly, it is recognised that herbal remedies may be used to treat or ameliorate various ailments in pet animals. Some herbal remedies have been developed for pet animals and these are all administered by means of tablets, powders or liquid extracts. Administration is generally by direct insertion into the mouth of the pet animal or following admixing the herbal remedy with the pet animal's meal. However, many herbal remedies have an unpleasant taste. Although this unpleasant taste is generally not a major concern with respect to humans, who can be persuaded to bear the unpleasant taste on the basis that they will benefit from taking the herbal remedy, the situation with pet animals is very different. Unfortunately, pet animals are rather fussy eaters and any degree of unpleasant taste is likely to result in complete rejection by the pet animal.

Flatulence is also a common problem among companion animals and the unpleasant odour therefrom constitutes a significant psycho-sociological problem in the animal-owner relationship. There may also be implications for gut health. Human studies have demonstrated the detrimental effects of toxic sulphur compounds present within intestinal gas on the health of the large intestine and such compounds have been implicated in the pathogenesis of ulcerative colitis.

The major components of intestinal gas which lead to flatulence are odourless gases; nitrogen, hydrogen, carbon dioxide, methane and oxygen. However, trace quantities of toxic sulphurous gases, such as hydrogen sulphide, are responsible for flatus odour. Sulphate-reducing bacteria (SRB) are the bacterial genus responsible for reducing sulphate to sulphide, generating hydrogen sulphide. Research in the human field has focused on the determination of gas volumes which lead to bloating and discomfort, whilst in the animal field research has centred around the characterisation of offensive odours within flatus.

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Several prior art documents disclose remedies to reduce the flatulence and/or the offensive odour associated therewith. For example, US Patent Nos. 5,716,641 and 5,679,376 disclose certain pharmaceutical compositions which are reported to reduce flatulence. Some of these compositions are based on simethicone.

The removal from food of materials believed to be strongly implicated in the production of flatulence (such as certain sugars and oligosaccharides) has also been described. For example, see US Patent Nos. 5,871,801 and 4,645,677.

The use of dietary supplements and additives to reduce flatulence odour is less well reported in the patent literature. There are a few examples, such as the addition of chitosan (e.g. see US Patent No. 5,773,427) or fumaric acid (e.g. see US 5,589,186) to the diet.

Salts of zinc are known to react with volatile sulphur gases, especially H<sub>2</sub>S (e.g. see US Patent No. 5,405,836). The use of dietary zinc salts to reduce the H<sub>2</sub>S content of intestinal gases has also been suggested in the published literature (e.g. see Suarez F.L., Springfield J, & Levitt MD (1998) "Identification of gases responsible for the odour of human flatus and evaluation of a device purported to reduce this odour". Gut. 43.100-104). The inclusion in the diet of extracts of Yucca schidigera has been shown to reduce the malodour of canine and feline faeces (e.g. see Lowe JA, Taylor AJ and Linforth R (1997) "The effect of Yucca schidigera extract on canine and feline faecal volatiles occuring concurrently with faecal aroma amelioration" Research in Veterinary Science, 63. 67-71), from which it is reasonable to infer that flatulence malodour would

also be reduced. Charcoal is well known as an adsorbent for noxious gases, and its ability to reduce flatus malodour within a cushion has been proven (again see article by Suarex et al). Charcoal is a component in a small number of orally administered odour reducing products currently on the market.

The present invention is directed towards alleviating some of the abovementioned problems. In particular, a first aspect of the invention is directed to providing a palatable pet food product which incorporates functional additives having medicinal, therapeutic or health benefits. Also, the invention is directed to such a pet food product which can be fed to a pet animal on a daily basis for improving and/or maintaining particular health aspects of the pet animal. The invention is also directed to a pet food product which is able to be easily administered in accordance with a predetermined dosage regime. [Further, the] Another aspect of the invention is directed to a process for manufacturing a palatable pet food product.

A further aspect of this invention is directed towards reducing flatulence odour in a pet animal.

## Summary of the Invention

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According to a first aspect of the invention there is provided a palatable pet food product including:

- a food substrate; and
- at least one health-enhancing functional additive, including a herbal extract,

wherein the at least one functional additive is present in a pre-determined concentration.

The food substrate includes dry ingredients and at least one liquid ingredient, typically in a ratio of about 2:1.

Generally, the dry ingredients include animal protein, carbohydrates and an anti-microbial agent. The animal protein generally constitutes about 50% (± 10%) by weight of the dry ingredients. The animal protein is usually derived from beef, pork, mutton, poultry, fish or a combination of these. The animal protein preferably includes gelatins. The carbohydrates generally include simple and complex carbohydrates. The complex carbohydrates typically consist of or include rice flour. The simple carbohydrates generally

consist of or include glucose, glycerol and/or sugar. The antimicrobial agent is preferably potassium sorbate.

The at least one liquid ingredient of the pet food product is preferably water and an antioxident. The antioxidant is generally rosemary extract. The water may constitute about 10 to about 20% by weight of the finished product. A particularly preferred amount of water is about 51% by weight of the finished product.

The pet food product may preferably include ingredients in the following proportions:

gelatine – from about 3 to about 7% by weight of finished product;

- glucose from about 2 to about 5% by weight of finished product;
- sugar from about 2 to about 5% by weight of finished product;
- glycerol from about 1 to about 4% by weight of finished product;
- potassium sorbate from about 0.2 to about 0.5% by weight of finished product;
- rosemary extract from about 0.01 to about 0.05% by weight of finished product; and
- water from about 10 to about 20% by weight of finished product.

The functional additives include at least one herbal extract and will generally include other additives which have medicinal, therapeutic or health benefits. The actual selection or composition of the functional additives in the pet food product will largely depend upon the particular health condition of the pet animal which is being addressed.

For instance, in one embodiment of the invention, the functional additives of the pet food product include L-glutamine, D-glucosamine sulphate, sugar beet pulp, inulin and slippery elm, said functional additives being provided in amounts sufficient to promote or maintain gastro-intestinal health when the pet food product is provided to a pet animal on a daily basis. These functional additives are preferably provided in the following amounts:

- L-glutamine from about 3 to about 5% by weight of finished product;
- D-glucosamine sulphate from about 3 to about 5% by weight of finished product;

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- sugar beet pulp from about 4 to about 8% by weight of finished product;
- inulin from about 3.5 to about 4.5% by weight of finished product;
   and
- slippery elm from about 1.5 to about 2.5% by weight of finished product.

It is particularly preferred that the functional additives are provided in the following amounts:

• L-glutamine - about 4% by weight of finished product;

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- D-glucosamine sulphate about 4% by weight of finished product;
- sugar beet pulp about 6% by weight of finished product;
- inulin about 3.9% by weight of finished product; and
- slippery elm about 2% by weight of finished product.

In another embodiment of the invention, the functional additives of the pet food product include vitamin E, vitamin B complex, evening primrose oil, vitamin C and marigold meal, said functional additives being provided in amounts sufficient to strengthen or maintain a pet animal's natural body defences (including immune system function) when the pet food product is provided to the pet animal on a daily basis. These functional additives are preferably provided in the following amounts:

- vitamin E about 0.7 to about 1.3% by weight of finished product;
- vitamin B complex about 0.15 to about 0.25% by weight of finished product;
- evening primrose oil about 1.5 to about 2.5% by weight of finished product;
- vitamin C about 0.7 to about 1.3% by weight of finished product;
- marigold meal about 0.4 to about 0.8% by weight of finished product.

It is particularly preferred that the above functional additives are provided in the following amounts:

vitamin E - about 1% by weight of finished product;

- vitamin B complex about 0.2% by weight of finished product;
- evening primrose oil about 2% by weight of finished product;



- vitamin C about 1% by weight of finished product;
- marigold meal about 0.6% by weight of finished product;

In a further embodiment of the invention, the functional additives of the pet food product include digestive enzymes, vitamin B complex, evening primrose oil, vitamin C, vitamin E, and dimethylglycine, said functional additives being provided in amounts sufficient to promote or maintain improved nutrition in senior/geriatric pet animal when the pet food product is provided to the pet animal on a daily basis. These functional additives are preferably provided in the following amounts:

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- digestive enzymes from about 0.7 to about 1.3% by weight of finished product;
- vitamin B complex from about 0.15 to about 0.25% by weight of finished product;

- evening primrose oil from about 0.4 to about 0.8% by weight of finished product;
- vitamin C from about 0.7 to about 1.3% by weight of finished product;
- vitamin E from about 0.7 to about 1.3% by weight of finished product; and

 dimethylglycine – from about 0.2 to about 0.6% by weight of finished product.

It is particularly preferred that the above functional additives are provided in the following amounts:

digestive enzymes – about 1% by weight of finished product;

vitamin B complex – about 0.2% by weight of finished product;

- evening primrose oil about 6% by weight of finished product;
- vitamin C about 1% by weight of finished product;
- vitamin E about 1% by weight of finished product; and
- dimethylglycine about 0.4% by weight of finished product.

In yet a further embodiment of the invention, the functional additives include vitamin E, vitamin A, zinc, vitamin C, calcium, phosphorus, probiotics and evening primrose oil, said functional additives being provided in amounts sufficient to promote or maintain improved growth and development in an

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actively growing pet animal when the pet food product is provided to the pet animal on a daily basis. It is preferred that the above functional additives are provided in the following amounts:

- vitamin E from about 0.7 to about 1.3% by weight of finished product;
- vitamin A from about 0.7 to about 1.3% by weight of finished product;
- zinc from about 0.07 to about 0.13% by weight of the finished product;
- vitamin C from about 0.7 to about 1.3% by weight of finished
   product;
- calcium from about 1.5 to about 2.5% by weight of finished product;
- phosphorus from about 1.5 to about 2.5% by weight of finished product;
- probiotics from about 1.5 to about 2.5% by weight of finished product; and
- evening primrose oil from about 1.5 to about 2.5% by weight of finished product.

It is particularly preferred that the above functional additives are provided in the following amounts:

- vitamin E –about 1% by weight of finished product;
- vitamin A about 1% by weight of finished product;
- zinc –about 0.1% by weight of finished product;
- vitamin C –about 1% by weight of finished product;
- calcium –about 2% by weight of finished product;
- phosphorus –about 2% by weight of finished product;
- probiotics –about 2% by weight of finished product; and
- evening primrose oil about 2% by weight of finished product.

In one further embodiment of the invention, the functional additives of the pet food product include valerian extract, gingko biloba extract, St John's Wort extract, vitamin B complex and magnesium, said functional additives being provided in amounts sufficient to promote or maintain reduction of stress

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and/or improved behavior of a pet animal when the pet food product is provided to the pet animal on a daily basis. It is preferred that the function additives are provided in the following amounts:

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- valerian extract from about 0.7 to about 1.3% by weight of finished product;
- gingko biloba extract from about 0.7 to about 1.3% by weight of finished product;
- St John's Wort extract from about 0.7 to about 1.3% by weight of finished product;
- vitamin B complex from about 0.15 to about 0.25% by weight of finished product;
- magnesium from about 0.15 to about 0.25% by weight of finished product.

In particular, it is preferred that the above functional additives are provided in the following amounts:

- valerian extract –about 1% by weight of finished product;
- gingko biloba extract –about 1% by weight of finished product;
- St John's Wort extract –about 1% by weight of finished product;
- vitamin B complex –about 0.2% by weight of finished product;
- magnesium –about 0.2% by weight of finished product.

In yet another embodiment of this invention, the functional additives of the pet food product include vitamin A, vitamin C, vitamin E, dimethylglycine, digestive enzymes and proanthocyanidin, said functional additives being provided in amounts sufficient to promote or maintain general health in a pet animal when the pet food product is provided to the pet animal on a daily basis. Preferably, the functional additives are provided in the following amounts:

- vitamin A from about 0.7 to about 1.3% by weight of finished product;
- vitamin C from about 0.7 to about 1.3% by weight of finished product;
- vitamin E from about 0.7 to about 1.3% by weight of finished product;

 dimethylglycine – from about 0.7 to about 1.3% by weight of finished product;

digestive enzymes - from about 0.4 to about 0.8% by weight of finished product;

 proanthocyanidin – from about 0.2 to about 0.6% by weight of finished product.

It is particularly preferred that the functional additives are provided in the following amounts:

vitamin A –about 1% by weight of finished product;

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- vitamin C –about 1% by weight of finished product;
- vitamin E -about 1% by weight of finished product;
- dimethylglycine -about 1% by weight of finished product;
- digestive enzymes -about 0.6% by weight of finished product;
- proanthocyanidin –about 0.4% by weight of finished product.

In a still further embodiment of the invention, the functional additives of the pet food product include vitamin B complex, vitamin C, vitamin E, folic acid, evening primrose oil and raspberry leaf extract, said functional additives being provided in amounts sufficient to promote or maintain improved nutrition during gestation/lactation when the pet food product is provided to the pet animal on a daily basis.

Preferrably, these functional additives are provided in the following amounts:

- vitamin B complex from about 0.07 to about 0.13% by weight of finished product;
- vitamin C from about 0.7 to about 1.3% by weight of finished product;
- vitamin E from about 0.7 to about 1.3% by weight of finished product;
- folic acid from about 0.0002 to about 0.0006% by weight of finished product;
- evening primrose oil from about 1.5 to about 2.5% by weight of finished product;

 raspberry leaf extract – from about 1.5 to about 2.5% by weight of finished product.

It is particularly preferred that the above functional additives are provided in the following amounts:

- vitamin B complex –about 0.1% by weight of finished product;
- vitamin C –about 1% by weight of finished product;
- vitamin E –about 1% by weight of finished product;
- folic acid –about 0.0004% by weight of finished product;
- evening primrose oil –about 2% by weight of finished product;
- raspberry leaf extract –about 2% by weight of finished product.

In a still further embodiment of the invention, the functional additives of the pet food product include vitamin B complex, vitamin C, vitamin E, magnesium, L-carnitine, dimethylglycine, glutamine, and at least one herbal extract selected from the group consisting of green tea, gingko biloba, gurana, ginseng and gotu kola, said functional additives being provided in amounts sufficient to improve exercise endurance and performance in a pet animal when the pet food product is provided to the pet animal on a daily basis. Preferably, these food additives are provided in the following amounts:

- vitamin B complex from about 0.15 to about 0.25% by weight of finished product;
- vitamin C from about 0.7 to about 1.3% by weight of finished product;
- vitamin E from about 0.7 to about 1.3% by weight of finished product;
- magnesium from about 0.4 to about 0.8% by weight of finished product;

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- L-carnitine from about 2 to about 4% by weight of finished product;
- dimethylglycine from about 0.6 to about 1.0% by weight of finished product;
- glutamine from about 3 to about 7% by weight of finished product,
   and
- herbal extract(s) from about 0.5 to about 1.5% by weight of finished product.

The above functional additives are still more preferably provided in the following amounts:

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- vitamin B complex –about 0.2% by weight of finished product;
- vitamin C –about 1% by weight of finished product;
- vitamin E –about 1% by weight of finished product;
- magnesium –about 0.6% by weight of finished product;
- L-carnitine –about 3% by weight of finished product;
- dimethylglycine –about 0.8% by weight of finished product;
- glutamine –about 5% by weight of finished product; and
- herbal extract(s) about 1% by weight of the finished product.

In one further embodiment of the invention, the functional additives of the pet food product include two or more additives selected from the group consisting of Yucca Shidigera extract, charcoal and salts of zinc, such as zinc acetate, said functional additives being provided in amounts sufficient to reduce flatulence odour when the pet food product is provided to a pet animal on a daily basis. It has been observed that the use of any two, or all three, of these functional additives in combination results in reduction of flatulence odour, with the specific combinations of zinc acetate and charcoal or zinc acetate, charcoal and Yucca Shidigera resulting in certain synergistic effects. Preferably, these functional additives are provided in the following amounts:

- Yucca Shidigera extract from about 0.07 to about 0.11% by weight of finished product;
- charcoal from about 10 to about 14% by weight of finished product;
- zinc acetate from about 0.5 to about 0.8% by weight of finished product.

It is particularly preferred that the above functional additives are provided in the following amounts:

- Yucca Shidigera extract about 0.09% by weight of finished product;
- charcoal about 11.94% by weight of finished product;
- zinc acetate about 0.63% by weight of finished product.

Preferably, the pet food product described above is provided in an easily divisible quantity, so as to facilitate administration to a pet animal of a desired amount of the product corresponding with a desired dosage of the at least one functional additive to be administered to the pet animal. Accordingly, the pet food product may be provided in the form of biscuits, in which case each biscuit contains a substantially identical, predetermined dosage of the at least one functional additive. Alternatively, the pet food product may be provided as a food bar, in which case the food bar has substantially uniform concentration of the at least one functional additive throughout the length of the bar. Preferably, the food bar includes markings, etchings or the like for indicating where the bar may be broken so as to provide the pet animal with the desired dosage of the functional additives.

According to a second aspect of the invention there is provided a process for manufacturing a palatable pet food product which contains a food substrate and at least one health enhancing functional additive, said process including the steps of:

- mixing dry ingredients including animal protein, carbohydrates and an antimicrobial agent;
- heating the mixture to between 50 to 80°C, preferably about 60°C, for about 5 to 15 minutes, preferably about 10 minutes;
- add at least one health-enhancing functional additive;
- mix the mixture for about 5 minutes;
- heat (in a separate container) liquid ingredients, including water and an antioxidant, to between 60 to 85°C, preferably about 75°C;
- add heated liquid ingredients to the mixture;
- heat resultant mixture to between 60 to 80°C, preferably about 75°C, for about 5 minutes; and

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• substantially immediately after this heating step cool the resultant mixture to between 40 to 60°C, preferably about 50°C.

This process may also include the step of molding the resultant mixture by impression molding techniques so as to form a predetermined size, shape and weight of the product. The process may also include the step of including markings, etchings or the like on the product so that the product can be relatively easily broken into smaller, desired pieces.

Preferably the health-enhancing functional additive used in the process includes a herbal extract.

It is especially preferred that this process is adapted to manufacture a palatable pet food product as described herein above.

## **EXAMPLES**

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The following examples are directed to the aspect of the invention directed to reducing flatulence odour in pet animals.

In order to demonstrate the benefits of the formulations of this aspect of the invention, two methods were used. The in vitro method is described in detail below under the heading, "In Vitro Method". The novel in-vivo method is described below under the heading "In Vivo Method".

### IN VITRO METHOD

This in vitro method has been used to measure in vitro hydrogen sulphide.

## Sample preparation

Active ingredient concentrations were chosen to correspond to levels incorporated into the treat. Ingredients were weighed into triplicate glass serum bottles containing 30 mls of fermentation media, bottles were capped with a cotton wool bung and covered with foil. Bottles were prepared with no active ingredient to act as controls. 200 mls of 10 mM sodium phosphate buffer, pH 7.4 was prepared in conical flasks, containing a flea, for faecal resuspension. Bottles were sterilised by autoclaving (15 min, 121°C) and placed into the anaerobic cabinet to attain anaerobic conditions (pre-reduction).

#### Faecal inoculation

Fresh faecal samples were collected, scored and weighed. A sample of faeces was freeze-dried to determine faecal dry weight. 20g of faeces were

added to the pre-reduced phosphate buffer within 15 min of defecation. The flask was placed on a magnetic stirrer (10 mins) in the anaerobic cabinet to generate a faecal slurry. Cotton wool bungs were removed and 3ml aliquots of faecal slurry were added to each serum bottle containing active ingredients and control bottles with no added active ingredient. This results in a 1% faecal inoculum per bottle. Bottles were hermetically sealed with rubber bungs and metal caps.

Bottles were inoculated in triplicate. Three bottles with no active ingredient were used as media and faeces controls. Three bottles with no active ingredient contained 1 ml of 10% molybdate, to inhibit sulphate reducing bacteria. All bottles were left to incubate for 24 hrs at 37°C.

The potential effects of the 3 active ingredients have been measured in terms of the total gas produced, and the level of hydrogen sulphide present in the *in vitro* fermentation broths.

## 15 <u>Hydrogen Sulphide</u>

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To determine hydrogen sulphide, the following procedure was followed.

- (i) A 1:4 dilution of broth in deoxygenated water was prepared.
- (ii) The sample was spun at 13,800g for 15 minutes at room temperature.
- (iii) Aliquots of the test sample were taken in order to provide test samples and faeces blanks, all stored on ice until analysis.

### Standard Curve

In order to identify the levels of hydrogen sulphide in a solution a standard curve within the range of 0-50ppm of sodium sulphide must be constructed for each set of samples analysed.

#### 25 Sample Analysis

To each standard, using Camlab Sulphide reagents:

- a. 1 ml of sulphide-1-reagent was added with mixing.
- b. 1 ml of sulphide-2-reagent was added with mixing.
- c. The absorbance was measured in a spectrophotometer at 670 nm.

## 30 Analysis of Test Samples

1. 2 mls of deoxygenated water were added to the faeces blanks and the absorbance at 670 nm measured.

2. Steps a - c above were repeated on the triplicate test samples in order to determine their sulphide concentration. Test samples were diluted as necessary in order to place them in the range of the standard solutions.

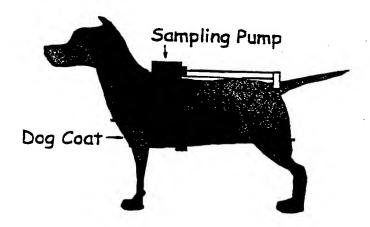
## IN VIVO METHOD

This in vivo method has been used to measure in vivo flatulence production.

The novel *in vivo* flatulence system employed in this study consists of a pump which is fitted into a coat worn by the dog which draws air from around the anal region (Fig A1). A plastic O ring containing holes 1 cm apart is placed around the tail and is positioned close to the anus. This is connected via a plastic tube to the pump. The pump has a sensor which detects sulphur gas.

The pumps were set to measure sulphur gas levels every 20 seconds so that a measure of sulphur gas produced by the dog over time was obtained.

Fig A1: Representation of the in vivo flatulence measurement



Consumer perception analysis has been carried out to identify the human detection limits of individual flatulence episodes recorded with the *in vivo* sulphur gas pump. Simple regression analysis was carried out to identify correlations between perceived and measurable flatulence parameters. A strong correlation (r = 0.9224) was identified between the human flatulence rating over a scale of 1-5 and *in vivo* sulphur gas levels (see Figure A2 below). An equation was generated that enables identification of the human detection levels of subsequent *in vivo* sulphur gas measures.

Human Perception Rating = 1.511124 \* Sulphur Gas (ppm) ^ 0.280379

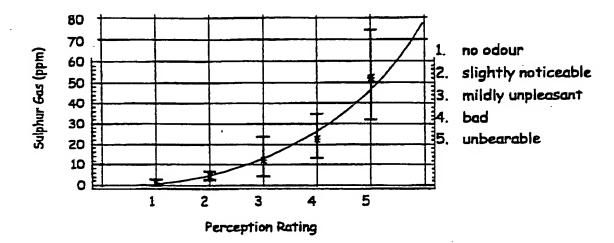
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The equation generated from consumer perception analysis was applied to sulphur gas readings obtained from the current trial and the human detection ratings of the recorded flatulence episodes were identified. An "episode" is any given period during which the sulphur gas reading is consistently greater than 1ppm. Sulphur gas levels of and below 1ppm were not detectable by the human odour judges.

## **EXAMPLE 1 - In vitro Experiment**

An in-vitro fermentation system was set up in order to assess the active ingredients for their potential to reduce hydrogen sulphide and total gas production. Ingredients were weighed into glass serum bottles containing fermentation media. Some bottles were also prepared without active ingredients in order to act as controls. Bottles were sterilised and placed into an anaerobic cabinet. Samples of faeces were collected, slurried, and aliquots of this slurry added to the control bottles and the bottles containing active ingredients - the bottles were then sealed and incubated for 24 hours at 37 C.

Hydrogen sulphide concentration was determined by the assay set out on page 15.

Table 1a shows the mean hydrogen sulphide levels that were present in fermentation broths following incubation with active ingredients. There were significant reductions in hydrogen sulphide with the individual active ingredients (p<0.05). Surprisingly, a synergistic effect of adding all 3 active ingredients was observed.

Table 1a Mean hydrogen sulphide (ppm) following treatment with active ingredients

Treatment	Hydrogen Sulphide (ppm)/(g) Wet Faeces (n=3)	
	Mean	SE
Media and Faeces Control	425.66	40.39
Yucca Shidigera	263.45	32.72
Zinc Acetate	158.03	25.47
Charcoal	128.91	14.87
All 3 Actives	58.06	0.92

## EXAMPLE 2 – In vitro Experiment

The experiment described above was repeated using binary mixtures of the actives.

Table 1b shows the mean hydrogen sulphide levels that were present in fermentation broths following incubation. The hydrogen sulphide levels for the control and the combination of all 3 actives are broadly similar to those determined in the previous example. The effect of the charcoal and zinc acetate appears, surprisingly to be synergistic.

Table 1b Mean hydrogen sulphide (ppm) following treatment with active ingredients

Treatment	Hydrogen Sulphide (ppm)/(g) Wet Weight Faeces (n=3)	
	Mean	SE
Media and Faeces Control	398	19.86
3 Actives	90.9	6.78
Charcoal and Yucca	174.63	44.07
Charcoal and Zinc	80.27	4.14
Zinc and Yucca	209.36	2.65

## 15 EXAMPLE 3 – In-vivo Experiment

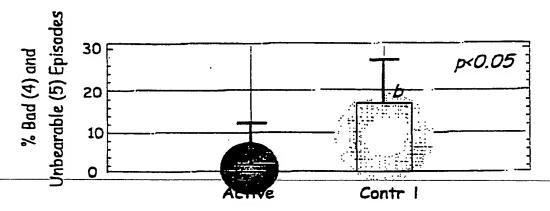
Details of the novel in-vivo method are given above under the heading "In-vivo Method". In these experiments a treat containing all 3 active ingredients was compared with a control containing no actives, as shown in the recipes below.

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Ingredient	%Inclusion	
	Active	Control
Poultry powders	15	15
Beef Tallow	6.5	6.5
Salt	1.8	1.8
Potassium Sorbate	0.2	0.2
Antioxidant	0.25	0.25
Water	9	9
Sugars	8	8
Glycol	2.3	2.3
Glycerol	9	9
Flours	41	41
Flavour	0.2	0.2
Soya oil	0.7	0.8
Yucca Extract	0.05	0
Zinc Acetate	0.32	0
Charcoal	5.97	0
Pregel Wheat Starch	0	6

Sulphur gas measures were collected for each dog in duplicate from active and control trial phases. These were converted into a consumer detection level using the rating equation (set out on page 16). The numbers of flatulence events in each of the rating classes (see 1 – 5 in the table on page 17) were determined as a percentage of the total events in each measurement period. The reduction in the percentage of bad (see 4 in the table on page 17) and unbearable (see 5 in the table on page 17) episodes between active and control treats was highly significant (p<0.05). The figure below illustrates the mean percentage of combined bad and unbearable episodes produced when dogs were fed active and control treats.

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Treat

## THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

- 1. A palatable pet food product including:
  - a food substrate; and
  - at least one health-enhancing functional additive, including a herbal extract;

wherein the at least one functional additive is present in a pre-determined concentration.

- 2. The pet food product of claim 1, wherein the food substrate includes dry ingredients and at least one liquid ingredient in a ratio of about 2:1.
- 3. The pet food product of claim 2, wherein the dry ingredients include animal protein, carbohydrates and an anti-microbial agent.
- 4. The pet food product of claim 3, wherein the animal protein constitutes about 50% ( $\pm 10\%$ ) by weight of the dry ingredients.
- 5. The pet food product of claim 3 or claim 4, wherein the animal protein is derived from beef, pork, mutton, poultry, fish or a combination of these.
- 6. The pet food product of claim 5, wherein the animal protein includes gelatins.
- 7. The pet food product of any one of claims 3 to 6, wherein the carbohydrates include simple and complex carbohydrates.
- 8. The pet food product of claim 7, wherein the complex carbohydrates include rice flour.
- 9. The pet food product of claim 7 or claim 8, wherein the simple carbohydrates include glucose, glycerol and/or sugar.

- 10. The pet food product of any one of claims 3 to 9, wherein the antioxidant is rosemary extract.
- 11. The pet food product of any one of claims 2 to 11, wherein the at least one liquid ingredient includes water and an antioxidant.
- 12. The pet food product of claim 11, wherein the water constitutes about 10 to about 20% by weight of the finished product.
- 13. The pet food product of any one of claims 3 to 10 containing the following proportions of dry ingredients:
  - gelatin from about 3% to about 7% by weight of finished product;
  - glucose from about 2% to about 5% by weight of finished product;
  - sugar from about 2% to about 5% by weight of finished product;
  - glycerol from about 1% to about 4% by weight of finished product;
  - potassium sorbate from about 0.2% to about 0.5% by weight of finished product; and
  - rosemary extract from about 0.01% to about 0.05% by weight of finished product; and
  - water from about 10 to about 20% by weight of finished product.
- 14. The pet food product of any one of claims 1 to 13, wherein the functional additives include L-glutamine, D-glucosamine sulphate, sugar beet pulp, inulin and slippery elm, said functional additives being provided in amounts sufficient to promote or maintain gastro-intestinal health when the pet food product is provided to a pet animal on a daily basis.
- 15. The pet food product of claim 14, wherein the functional additives are provided in the following amounts:
  - L-glutamine from about 3 to about 5% by weight of finished product;

- D-glucosamine sulphate from about 3 to about 5% by weight of finished product;
- sugar beet pulp from about 4 to about 8% by weight of finished product;
- inulin from about 3.5 to about 4.5% by weight of finished product;
   and
- slippery elm from about 1.5 to about 2.5% by weight of finished product.
- 16. The pet food product of claim 15, wherein the functional additives are provided in the following amounts:
  - L-glutamine about 4% by weight of finished product;
  - D-glucosamine sulphate about 4% by weight of finished product;
  - sugar beet pulp about 6% by weight of finished product;
  - inulin about 3.9% by weight of finished product; and
  - slippery elm about 2% by weight of finished product.
- 17. The pet food product of any one of claims 1 to 13, wherein the functional additives include vitamin E, vitamin B complex, evening primrose oil, vitamin C and marigold meal, said functional additives being provided in amounts sufficient to strengthen or maintain a pet animal's natural body defences (including immune system function) when the pet food product is provided to the pet animal on a daily basis.
- 18. The pet food product of claim 17, wherein the functional additives are provided in the following amounts:
  - vitamin E about 0.7 to about 1.3% by weight of finished product;
  - vitamin B complex about 0.15 to about 0.25% by weight of finished product;
  - evening primrose oil about 1.5 to about 2.5% by weight of finished product;
  - vitamin C about 0.7 to about 1.3% by weight of finished product;

- marigold meal about 0.4 to about 0.8% by weight of finished product;
- 19. The pet food product of claim 18, wherein the functional additives are provided in the following amounts:
  - vitamin E about 1% by weight of finished product;
  - vitamin B complex about 0.2% by weight of finished product;
  - evening primrose oil about 2% by weight of finished product;
  - vitamin C about 1% by weight of finished product;
  - marigold meal about 0.6% by weight of finished product;
- 20. The pet food product of any one of claims 1 to 13, wherein the functional additives include digestive enzymes, vitamin B complex, evening primrose oil, vitamin C, vitamin E, and dimethylglycine, said functional additives being provided in amounts sufficient to promote or maintain improved nutrition in a senior/geriatric pet animal when the pet food product is provided to the pet animal on a daily basis.
- 21. The pet food product of claim 20, wherein the functional additives are provided in the following amounts:
  - digestive enzymes from about 0.7 to about 1.3% by weight of finished product;
  - vitamin B complex from about 0.15 to about 0.25% by weight of finished product;
  - evening primrose oil from about 4 to about 8% by weight of finished product;
  - vitamin C from about 0.7 to about 1.3% by weight of finished product;
  - vitamin E from about 0.7 to about 1.3% by weight of finished product; and
  - dimethylglycine from about 0.2 to about 0.6% by weight of finished product.

- 22. The pet food product of claim 21, wherein the functional additives are provided in the following amounts:
  - digestive enzymes about 1% by weight of finished product;
  - vitamin B complex about 0.2% by weight of finished product;
  - evening primrose oil about 6% by weight of finished product;
  - vitamin C about 1% by weight of finished product;
  - vitamin E about 1% by weight of finished product; and
  - dimethylglycine about 0.4% by weight of finished product.
- 23. The pet food product of any one of claims 1 to 13, wherein the functional additives include vitamin E, vitamin A, zinc, vitamin C, calcium, phosphorus, probiotics and evening primrose oil, said functional additives being provided in amounts sufficient to promote or maintain improved growth and development in an actively growing pet animal when the pet food product is provided to the pet animal on a daily basis.
- 24. The pet food product of claim 23, wherein the functional additives are provided in the following amounts:
  - vitamin E from about 0.7 to about 1.3% by weight of finished product;
  - vitamin A from about 0.7 to about 1.3% by weight of finished product;
  - zinc from about 0.07 to about 0.13% by weight of the finished product;
  - vitamin C from about 0.7 to about 1.3% by weight of finished product;
  - calcium from about 1.5 to about 2.5% by weight of finished product;
  - phosphorus from about 1.5 to about 2.5% by weight of finished product;

- probiotics from about 1.5 to about 2.5% by weight of finished product; and
- evening primrose oil from about 1.5 to about 2.5% by weight of finished product.
- 25. The pet food product of claim 24, wherein the functional additives are provided in the following amounts:
  - vitamin E –about 1% by weight of finished product;
  - vitamin A about 1% by weight of finished product;
  - zinc –about 0.1% by weight of finished product;
  - vitamin C –about 1% by weight of finished product;
  - calcium –about 2% by weight of finished product;
  - phosphorus –about 2% by weight of finished product;
  - probiotics –about 2% by weight of finished product; and
  - evening primrose oil about 2% by weight of finished product.
- 26. The pet food product of any one of claims 1 to 13, wherein the functional additives include valerian extract, gingko biloba extract, St John's Wort extract, vitamin B complex and magnesium, said functional additives being provided in amounts sufficient to promote or maintain reduction of stress and/or improved behavior of a pet animal when the pet food product is provided to the pet animal on a daily basis.
- 27. The pet food product of claim 26, wherein the functional ingredients are provided in the following amounts:
  - valerian extract from about 0.7 to about 1.3% by weight of finished product;
  - gingko biloba extract from about 0.7 to about 1.3% by weight of finished product;
  - St John's Wort extract from about 0.7 to about 1.3% by weight of finished product;

- vitamin B complex from about 0.15 to about 0.25% by weight of finished product;
- magnesium from about 0.15 to about 0.25% by weight of finished product.
- 28. The pet food product claim 27, wherein the functional additives are provided in the following amounts:
  - valerian extract –about 1% by weight of finished product;
  - gingko biloba extract –about 1% by weight of finished product;
  - St John's Wort extract –about 1% by weight of finished product;
  - vitamin B complex –about 0.2% by weight of finished product;
  - magnesium –about 0.2% by weight of finished product.
- 29. The pet food product of any one of claims 1 to 13, wherein the functional additives include vitamin A, vitamin C, vitamin E, dimethylglycine, digestive enzymes and proanthocyanidin, said functional additives being provided in amounts sufficient to promote or maintain general health in a pet animal when the pet food product is provided to the pet animal on a daily basis.
- 30. The pet food product of claim 29, wherein the functional additives are provided in the following amounts:
  - vitamin A from about 0.7 to about 1.3% by weight of finished product;
  - vitamin C from about 0.7 to about 1.3% by weight of finished product;
  - vitamin E from about 0.7 to about 1.3% by weight of finished product;
  - dimethylglycine from about 0.7 to about 1.3% by weight of finished product;
  - digestive enzymes from about 0.4 to about 0.8% by weight of finished product;

- proanthocyanidin from about 0.2 to about 0.6% by weight of finished product.
- 31. The pet food product of claim 30, wherein the functional additives are provided in the following amounts:
  - vitamin A –about 1% by weight of finished product;
  - vitamin C –about 1% by weight of finished product;
  - vitamin E –about 1% by weight of finished product;
  - dimethylglycine –about 1% by weight of finished product;
  - digestive enzymes –about 0.6% by weight of finished product;
  - proanthocyanidin –about 0.4% by weight of finished product.
- 32. The pet food product of any one of claims 1 to 13, wherein the functional additives include vitamin B complex, vitamin C, vitamin E, folic acid, evening primrose oil and raspberry leaf extract, said functional additives being provided in amounts sufficient to promote or maintain improved nutrition during gestation/lactation when the pet food product is provided to the pet animal on a daily basis.
- 33. The pet food product of claim 32, wherein the functional additives are provided in the following amounts:
  - vitamin B complex from about 0.07 to about 0.13% by weight of finished product;
  - vitamin C from about 0.7 to about 1.3% by weight of finished product;
  - vitamin E from about 0.7 to about 1.3% by weight of finished product;
  - folic acid from about 0.0002 to about 0.0006% by weight of finished product;
  - evening primrose oil from about 1.5 to about 2.5% by weight of finished product;

- raspberry leaf extract from about 1.5 to about 2.5% by weight of finished product.
- 34. The pet food product of claim 33, wherein the functional additives are provided in the following amounts:
  - vitamin B complex –about 0.1% by weight of finished product;
  - vitamin C –about 1% by weight of finished product;
  - vitamin E –about 1% by weight of finished product;
  - folic acid –about 0.0004% by weight of finished product;
  - evening primrose oil –about 2% by weight of finished product;
  - raspberry leaf extract –about 2% by weight of finished product.
- 35. The pet food product of any one of claims 1 to 13, wherein the functional additives include vitamin B complex, vitamin C, vitamin E, magnesium, L-carnitine, dimethylglycine, glutamine and at least one herbal extract selected from the group consisting of green tea, gingko biloba, gurana, ginseng and gotu kota, said functional additives being provided in amounts sufficient to improve exercise endurance and performance in a pet animal when the pet food product is provided to the pet animal on a daily basis.
- 36. The pet food product of claim 35, wherein the functional additives are provided in the following amounts:
  - vitamin B complex from about 0.15 to about 0.25% by weight of finished product;
  - vitamin C from about 0.7 to about 1.3% by weight of finished product;
  - vitamin E from about 0.7 to about 1.3% by weight of finished product;
  - magnesium from about 0.4 to about 0.8% by weight of finished product;
  - L-carnitine from about 2 to about 4% by weight of finished product;

- dimethylglycine from about 0.6 to about 1.0% by weight of finished product;
- glutamine from about 3 to about 7% by weight of finished product;
   and
- herbal extract(s) from about 0.5 to about 1.5% by weight of finished product.
- 37. The pet food product of claim 36, wherein the functional additives are provided in the following amounts:
  - vitamin B complex –about 0.2% by weight of finished product;
  - vitamin C –about 1% by weight of finished product;
  - vitamin E –about 1% by weight of finished product;
  - magnesium –about 0.6% by weight of finished product;
  - L-carnitine –about 3% by weight of finished product;
  - dimethylglycine –about 0.8% by weight of finished product;
  - glutamine -about 5% by weight of finished product; and
  - herbal extract(s) from about 0.5 to about 1.5% by weight of finished product.
- 38. The pet food product of any one of claims 1 to 13, wherein the functional additives include two or more additives selected from the Yucca Shidigera extract, charcoal and salts of zinc [acetate], said functional additives being provided in amounts sufficient to reduce flatulence odour when the pet food product is provided to a pet animal on a daily basis.
- 39. The pet food product of claim 38, wherein the functional additives are provided in the following amounts:
  - Yucca Shidigera extract from about 0.07 to about 0.11% by weight of finished product;
  - charcoal from about 10 to about 14% by weight of finished product;

- zinc acetate from about 0.5 to about 0.8% by weight of finished product.
- 40. The pet food product of claim 39, wherein the functional additives are provided in the following amounts:
  - Yucca Shidigera extract about 0.09% by weight of finished product;
  - charcoal about 11.94% by weight of finished product;
  - zinc acetate about 0.63% by weight of finished product.
- 41. The pet food product of any one of claims 1 to 40, wherein the product is provided in an easily divisible quantity so as to facilitate administration to a pet animal of a desired amount of the product corresponding with a desired dosage of the at least one functional additive to be administered to the pet animal.
- 42. The pet food product of claim 41, wherein the pet food product is provided in the form of biscuits, each biscuit containing a substantially identical, predetermined dosage of the at least one functional additive.
- 43. The pet food product of claim 41, wherein the pet food product is provided in the form of a food bar, having substantially uniform concentration of the at least one functional additive throughout the length thereof.
- 44. The pet food product of claim 43, wherein the food bar includes markings, etchings or the like for indicating where the food bar may be broken so as to provide the pet animal with a desired dosage of the at least one functional additive.
- 45. A process for manufacturing a palatable pet food product which contains a food substrate and at least one health-enhancing functional additive, said process including the steps of:

- mixing dry ingredients including animal protein, carbohydrates and an antimicrobial agent;
- heating the mixture to between 50 to 80°C, preferably about 60°C, for about 5 to 15 minutes, preferably about 10 minutes;
- add at least one health-enhancing functional additive;
- mix the mixture for about 5 minutes;
- heat (in a separate container) liquid ingredients, including water and an antioxidant, to between 60 to 85°C, preferably about 75 °C;
- add heated liquid ingredients to the mixture;
- heat resultant mixture to between 60 to 80°C, preferably about 75°C, for about 5 minutes; and
- substantially immediately after this heating step cool the resultant mixture to between 40 to 60°C, preferably about 50°C.
- 46. The process of claim 45 further including the step of molding the resultant mixture by impression molding techniques so as to form a predetermined size, shape and weight of the product or pieces of the product.
- 47. The process of claim 45 or claim 46 further including the step of making markings, etchings or the like on the product so as to enable the product to be easily broken into pieces of a particular size.
- 48. A pet food product made according to the process of any one of claims 45 to 47.

## <u>DATED</u> this 20<sup>th</sup> day of January 2000 <u>EFFEM FOODS PTY LTD</u>

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